Testimony of Michael Walsh
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Before the Health Subcommittee of the House Energy and Commerce Committee
"FDA User Fees 2012: Hearing on Issues Related to Accelerated Approval, Medical Gas, Antibiotic Development and Downstream Pharmaceutical Supply Chain"
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Mr. Chairman, Mr. Ranking Member, thank you for inviting me to testify today. My name is Mike Walsh. I am President of LifeGas, which is part of Linde North America. Linde is headquartered in New Jersey and has about 4,500 employees in the United States. I am here today testifying on behalf of the Compressed Gas Association, of which Linde is a member. CGA represents companies engaged in the manufacture and distribution of compressed gases, including medical gases.

The Compressed Gas Association was founded in 1913 and currently has more than 120 member companies. CGA serves as the safety standard setting organization for the medical gas industry. The medical gas companies in our coalition employ about 21,000 people in 4,500 different locations, half of which are small businesses. I personally entered into the medical gas industry as a small businessman.

Linde and other members of the Compressed Gas Association provide medical gases that are used by doctors primarily for respiratory care. You will find our products in hospitals, clinics, emergency centers, long-term care settings, dentist offices and in homes through homecare companies across the country.

On behalf of the CGA, I want to offer my thanks to Congressmen Leonard Lance and Chris Murphy for introducing the Medical Gas Safety Act. Your leadership role on this issue has been pivotal. I also want to thank Chairman Pitts and Ranking Member Pallone for your willingness to address these issues in the very important bill you are working on.

Naturally, I also want to thank Chairman Upton and Ranking Member Waxman of the full committee as well.

Medical gases like oxygen, helium, and nitrogen are used by medical practitioners as prescription drugs every day by over a million patients for a variety of conditions. Medical oxygen has been used for more than a century. Medical gases were in use for decades before FDA was created and the New Drug Application process was initiated

Here is the key point: Medical gases have a long history of safe and effective use. The most common ones are derived from the air that we breathe every day. These common medical gases are a unique class of drug products that are different from traditional pharmaceuticals in a number of ways:

- They have different properties than traditional prescription drugs;
- They have different delivery methods;
- They are manufactured differently;
- Their containers and labeling are different; and
- Medical gas manufacturers make no medical claims for the vast majority of medical gases, which is very different from traditional prescription drugs.

However, FDA currently regulates medical gases with the same regulatory system as traditional pharmaceuticals. This has created significant and growing regulatory issues. These practical issues create uncertainty and drive up compliance costs for our industry. Medical gases need a separate regulatory system that takes into account their unique characteristics.

The Medical Gas Safety Act addresses a number of critical regulatory issues facing the medical gas industry. It establishes an appropriate approval process for medical gases. It

requires the creation of separate regulations for medical gases. It ensures that FDA fees do not disproportionately impact medical gas manufacturers, many of whom are small businesses. This legislation will create regulatory certainty for our industry. It will ensure that patients and the medical community have access to these life saving products. It will remove the current ambiguity regarding the federal regulation of medical gases for federal and state inspectors.

The FDA has recognized the unique nature of medical gases for a long time. Until now, FDA has generally used its "enforcement discretion" not to require medical gases to go through the new drug application process. Recently, the FDA began the "Unapproved Drugs Initiative," which is intended to eliminate all "unapproved drugs" from the marketplace, including medical gases. If the Unapproved Drug Initiative is applied to medical gases, this would remove access for patients to medical gases like Oxygen.

Recent changes in enforcement policies related to the export of unapproved drugs have also created serious challenges for the industry. The FDA has started requiring medical gases being exported to be labeled as "unapproved." This has caused some customers to cancel or delay orders from U.S. companies, even though these products are recognized as safe and effective. As a result, these customers may be buying their products from other countries where medical gases are not labeled as "unapproved." The Medical Gas Safety Act would address this issue and establish an appropriate approval process for medical gases.

Similarly, the regulatory system in place for medical gases does not take into account the unique characteristics of medical gases. In response to concerns raised by the Compressed Gas Association, the FDA stated in 1976 in the preamble to the original Current Good Manufacturing Practices rulemaking that they intend to develop separate regulations for medical gases. No such regulations have been developed. This lack of

specific regulations for medical gases has resulted in decades of unwritten enforcement discretion for federal and state regulators and uncertainty for the regulated industry.

For example, FDA has told the industry it will not enforce the expiration date requirement for medical gases. However federal and state inspectors often try to enforce expiration date requirements on medical gases, which never expire. For instance, Oxygen is an element of the periodic table. By its basic properties it will never expire. However current FDA regulations require all drugs, including medical gases like Oxygen, to have an expiration date.

The Medical Gas Safety Act would create an appropriate approval process for medical gases that do not have FDA approval, but have been widely used and accepted as safe and effective. It would set up a regulatory framework for such medical gases that would address issues like labeling requirements and good manufacturing practice requirements. These issues are very important. It would create an advisory committee to give expert advice to the FDA. They could share with FDA the vast library of appropriate safety standards that have been created by CGA. And it would ensure that fees for medical gases are proportional to the actual regulatory costs for a group of products that historically have a low risk profile.

This legislation will provide a clear, targeted regulatory structure for medical gases. Creating a process for medical gases to become approved drugs and establishing specific regulations for medical gases will reduce uncertainty, improve compliance and improve safety in what is already a very safe industry. It will benefit doctors, patients, distributors, manufacturers and even regulators. It will ensure safety and continued availability of extremely important products used every day. I applaud all of you again for your willingness to address these important and longstanding regulatory issues.

Thank you again, on behalf of CGA, for the opportunity to testify. I will be glad to answer any questions you might have.